IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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| BOARD OF REGENTS, THE UNIVERSITY OF TEXAS SYSTEM and TISSUEGEN, INC., | ) | |
| *Plaintiffs*, | ) | C.A. No. 1:18-cv-00392-GBW |
| v. | ) | |
| BOSTON SCIENTIFIC CORPORATION, | ) | |
| *Defendant*. | ) | |

**PLAINTIFFS' BRIEF IN SUPPORT OF MOTION TO STRIKE TESTIMONY AND FOR A LIMITING INSTRUCTION REGARDING BOSTON SCIENTIFIC'S ARGUMENTS ON THE METHOD OF MANUFACTURING A FIBER**

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## I. NATURE AND STAGE OF THE PROCEEDINGS

Trial on this matter commenced on January 25, 2022.

## II. SUMMARY OF ARGUMENT

1. Boston Scientific intentionally, repeatedly, and pervasively violated the Court's orders prohibiting Boston Scientific from arguing or presenting evidence that the fiber as claimed by the '296 patent is limited to a particular method of manufacturing. The evidence should be struck from the record.

2. Additionally, a curative limiting instruction to the jury is required to avoid unfair prejudice to Plaintiffs in light of this testimony that was intentionally injected into the record in violation of this Court's order with the intent to confuse and mislead the jury on a core issue in the case – the very thing the Court's order stated it was being entered to avoid. The prejudice to The University and TissueGen is not credibly deniable.

## III. STATEMENT OF FACTS

The issue of whether the fiber claimed in the '296 patent ***requires*** a spinning process has been an issue in multiple motions before this Court.[1] In every instance, the Court and its predecessor has correctly ruled that the fiber in the '296 patent is not required to be made through a spinning process.[2] Boston Scientific refuses to accept, much less respect these rulings.

Most recently and specifically relevant here, the Court granted Plaintiffs' Motion *In Limine* #3 to the extent that "BSC argues or BSC's expert asserts either that fibers must have a common molecular orientation or ***that Claim 1 of U.S. Patent No. 6,596,296 ('296 Patent) is limited by a***

[1] *See, e.g.,* D.I. 202 at ¶¶16-18; D.I. 245 at 1-4, 11-12; *see generally* D.I. 246.
[2] D.I. 255 at 11-12, 15-16; D.I. 276 at 1-2; *see* D.I. 288 at 63:9-65:24 (the Court's instructions on how to interpret Limine Order #3 could not have been clearer); *see also* D.I. 89 at 11-12, 29, D.I. 90 (predecessor Court did not include a method of manufacture in claim constructions)

***method of manufacturing***."[3] In direct and potentially contemptuous violation of the Limine 3 Order and all those going before it holding similarly, Boston Scientific, through the live testimony of its expert Dr. Mooney intentionally, repeatedly and pervasively communicated to the jury that a fiber as claimed under the '296 patent and every other form of polymer fiber ***must*** be made via a spinning process.[4] The intent to violate the Court's orders through the testimony of Dr. Mooney is obvious for two reasons: (1) it was pervasive and repeated throughout his testimony; and (2) Dr. Mooney repeatedly "volunteered" that spinning is required to make ***all fibers*** in nonresponsive answers.[5] This conduct is all the more egregious when the Court's ruling on the Mooney demonstratives is considered.[6] The Court excluded slides from Dr. Mooney's presentation that attempted to indicate a fiber must be made, can only be made using a spinning process.[7] Dr. Mooney was present for these rulings. Despite being directly instructed by the Court not to get into multiple topics in his testimony (a fiber requires a spinning process, an amorphous polymer

[3] D.I. 276 at 1-2 (the "Limine 3 Order," emphasis added).
[4] *See, e.g.*, Trial Transcript at 696:20-24; 696:25-697:7; 698:5-12; 698:13-700:8; 725:12-14; 702:10-703:22; 725:12-14.
[5] It appears Dr. Mooney was coached to volunteer this information so the Boston Scientific lawyers could get the information in without asking questions that would draw an objection. The Court should require Boston Scientific to produce all communications with Dr. Mooney and all documents provided to him (testimonial outlines, questions and his expected answers) to determine if they indicate that the pre-planned content of his testimony was to include the "fibers can only be made by spinning" testimony. That material can be produced for *in camera* inspection and Dr. Mooney and the Boston Scientific lawyers can provide a declaration that the *in camera* production is complete. This goes to the heart of whether the conduct was contemptuous. At the very least, the production will reveal whether Dr. Mooney was ever instructed by Boston Scientific's counsel to follow the Court's orders and avoid testimony that fibers can only be made by a spinning process.
[6] *See* Trial Transcript at 540:25-541:7; 541:20-543:22. Dr. Mooney was also told not to testify that an amorphous polymer cannot be used to make a fiber, and he ignored and violated those instructions as well. *See* Transcript 718:19-720:13; 789:24-790:3; 804:20-805:2 (Dr. Mooney literally provided in his testimony the content of the slides the Court excluded, demonstrating his and Boston Scientific's contempt of the Court's rulings.)
[7] *See* Ex. 1, excluded Mooney slides.

is not suitable for making a fiber), Dr. Mooney and Boston Scientific proceed to do exactly that, including providing in testimony the content of excluded slides. This cannot stand.

What the Court allowed Boston Scientific to do is offer testimony regarding its SYNERGY™ stent manufacturing process, and then allow Dr. Mooney to state that the specific process used by Boston Scientific so identified cannot result in a fiber as claimed.[8] Dr. Mooney's testimony on the Boston Scientific process was cursory at best and blatantly misrepresented it as being analogous to rolling paint onto a wall.[9] The actual Boston Scientific process is a press coating process. The metal of the SYNERGY™ stents is plasma-treated to a very precise degree to make their outside surface receptive to attract the exact amount of the "sticky polymer" on a precisely designed polymer pool. The pre-treated stents are then placed ***over*** a mandrel (the paint roller in the misleading Boston Scientific analogy). The mandrel with the stent on the outside is then lowered at very precise specified pressure to reach a precise depth into a sticky polymer pool whose thickness, temperature and other variables are also tightly controlled. At that point, the conveyor on which the polymer pool sits is advanced at a very controlled and prescribed speed so that the mandrel with the stent on its outside surface freely revolves one time so the plasma-treated metal stent "picks up" a very precisely controlled amount of polymer to cover the outside surface and some side surface based on the depth the stent is inserted into the polymer pool. That pressing process leaves the impression in the polymer pool the Court saw on the video.[10] The final "fiber" structure forms on the stent as the polymer dries. This press-coating process is why the fiber on the SYNERGY™ stents looks like a "haircut" and not a flat painted surface. ***That process was never described by Dr. Mooney in his direct testimony*** despite the fact it likely took 30 seconds

[8] D.I. 288 at 63:9-65:24.
[9] *See, e.g.*, Trial Transcript at 715:13-716:6; 733:4-14.
[10] JTX004.

for the Court to read it here. The sum total of Dr. Mooney's testimony regarding the SYNERGY™ stent's manufacturing process is included below which is factually and technically incorrect and was intended as such to materially mislead and confuse the jury:

Q. And then in the process you talked about how the bare-metal stent is dipped into this liquid coating?

A. Yes.

Q. And the liquid coating does -- or the liquid solution doesn't have any polymers, nothing thread-like?

A. No, nothing thread-like there.

Q. And we watched this clip, but when the stent is dipped in the liquid coating, does -- is any thread-like structure or any fiber formed from that process?

A. No, it's dipped in a liquid. And when the stent then is rolled and comes back up, it's still a liquid, but now it's a liquid that's coating the stent.

Q. Let us watch this here.

(Video clip played for the jury.)

BY MR. GRIMSRUD:

Q. So the stent is -- it's dipped in this liquid, rolled, and that's how it's coated?

A. Yeah. And then the last step is it's dried, so the solvent basically dries off like paint. So then you have basically this coating.

Q. And we've used this analogy of taking a paint roller, if you imagined a pool of paint and you rolled your paint roller through the paint, you get a coating of paint on the outside of it. Obviously, the liquid solution is not paint, but how does that analogy compare to this process?

A. I think it's a very appropriate analogy, very accurate analogy.[11]

Contrast Dr. Mooney's one minute of inaccurate, misleading and confusing testimony about Boston Scientific's manufacturing process for the SYNERGY™ stents to his largely

[11] Trial Transcript at 723:21-724:22.

unresponsive spinning testimony about the process required to make ***all*** fibers[12], the testimony Boston Scientific was told repeatedly was off-limits:

Q. And so will a -- you know, a polymer, will a polymer just spontaneously form a fiber on its own?

A. No. [then a nonresponsive answer] No, you ***actually have to put it through a specific type of process to get a fiber*** formed from these polymers.[13]

Dr. Mooney went further:

Q. And let's talk about some examples of processes for making a fiber. What are some examples of processes that, you know, engineers use to make polymers into fibers?

A. Yup, so ***these are all extrusion processes, and we call them spinning***, when we make fibers. And, you know, we've actually seen or heard these terms now a number of times already, ***"melt-spinning," "wet-spinning," "dry-spinning," "electro-spinning."***[14]

This testimony directly and unambiguously violates the Court's orders. Dr. Mooney told the jury ***all*** processes to make a fiber must be extrusion/spinning processes in non-responsive answer to a question that asked for examples not a statement that limited fibers to only one type of process. This again allowed no opportunity for the University's counsel to object before the testimony was published. This pattern would tend to indicate that Dr. Mooney was coached to volunteer as often as he could that the only process to make a fiber is one that involves spinning.

Dr. Mooney went on violating the Court's orders:

Q. Does Boston Scientific's manufacturing process for putting the coating on the SYNERGY stent, does it involve any type of spinning?

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[12] Trial Transcript at 689:15-22. Dr. Mooney claimed to be following the Court's claim construction for fiber, which he obviously was not doing. When asked if he agreed with the Court's claim construction ***on direct***, he gave an evasive misleading response. *Id* at 688:22-689:6.

[13] *Id.* at 696:20-24. At this point an objection would have required a sidebar eating up time and it would have emphasized the testimony.

[14] *Id.* at 696:25-697:7. Again, Dr. Mooney told the jury that all fibers must be made through a spinning process, which is not just technically wrong – and contradicts Boston Scientific's corporate representative testimony from Dr. Chen – but clearly intended to violate both the claims construction order and the Limine 3 Order.

A. No. [then another nonresponsive answer] ***There's no spinning processes that are utilized in the SYNERGY stent coating***.

Q. No melt-spinning, wet-spinning, dry-spinning, electro-spinning?

A. No, none of these.[15]

Here, Dr. Mooney is not limiting himself as ordered to testify that Boston Scientific's process (that he never described accurately) does not result in a thread-like structure. Instead, he is saying that because only spinning processes can result in a fiber *ipso facto* Boston Scientific's press coating process ***cannot create a fiber*** does not infringe based on the process. That entire line of testimony is bad faith, potentially contemptuous (if planned in advance) and indicates an intent by at least Dr. Mooney to mislead, confuse and prejudice the jury.

Dr. Mooney continued:

Q. And did Boston Scientific in their manufacturing use any type of spinning?

A. No, [then yet another nonresponsive answer] they did not use any spinning process.[16]

This is (at least) a third time, Dr. Mooney testified on a process Boston Scientific ***does not use*** instead of stating what was allowed, testimony that the process Boston Scientific actually uses ***does not result*** in an infringing design. The University objected that none of this testimony was supported by any foundation.[17]

No party should be allowed to violate the spirit or wording of this Court's orders limiting the presentation of irrelevant, misleading, confusing and prejudicial evidence, especially where, as here, the Court has repeatedly and consistently expressly rejected attempts to introduce such

[15] *Id.* at 698:5-12 (emphasis added).
[16] *Id.* at 725:12-14.
[17]Trial Transcript, 747:20-21; 749:12-13. Apparently, Dr. Mooney concluded he did not need to study or understand the Boston Scientific process (or explain it to the jury) beyond that it did not involve spinning. This is again an argument that violates the Court's orders.

evidence.[18] Such arguments trespass on the Court's exclusive authority to determine the legal issues of the scope and meaning of patent claim terms and should be excluded.[19]

The risk of unfair prejudice to the University and TissueGen resulting from these obviously intentional, pervasive and pre-planned attempts to skirt the Court's orders and present the jury a false, rejected interpretation of Court's claim constructions through Dr. Mooney's nonresponsive testimony is very high. In some instances, unfair prejudice can, in part, be remedied by a limiting instruction to the jury.[20] Here, the conduct is so egregious and pervasive the only fair remedy is to strike the testimony and instruct the jury to disregard it. The skunk Boston Scientific intentionally and repeatedly threw into the jury box cannot be retrieved (or the odor removed) with a limiting instruction alone. The University moves the Court to strike Dr. Mooney's testimony on the subject of fibers, instruct the jury to disregard it in its entirety and prohibit Boston Scientific from recalling Dr. Mooney on the "fiber issue."[21]

Alternatively, and without waiving any objections that Dr. Mooney's testimony on the issue of fiber be struck completely, the University and TissueGen suggest the following construction:

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[18] *See RSB Spine, LLC v. DePuy Synthes Sales, Inc.*, 2022 U.S. Dist. LEXIS 209373 (D. Del. 2022) ("Expert testimony that contradicts the Court's claim construction should be excluded."); *Minerva Surgical, Inc. v. Hologic, Inc.*, 2021 U.S. Dist. LEXIS 134773 at *18 (D. Del. 2022) ("The opinions of a patent infringement expert who applies an erroneous claim construction are inadmissible.") *Sprint Commc'ns Co. L.P. v. Cox Commc'ns Inc.*, 302 F. Supp. 3d 597, 619-21, 624 (D. Del. 2017) (excluding "expert testimony that is inconsistent with the Court's claim construction [as] unreliable and unhelpful to the finder of fact"); *Liquid Dynamics Corp. v. Vaughan Co.*, 449 F.3d 1209, 1224 n.2 (Fed. Cir. 2006) (affirming exclusion of expert testimony as "irrelevant because it was based on an impermissible claim construction" and "could prejudice and confuse the jury")

[19] *Id.*

[20] *See Abbott Point of Care, Inc. v. Epocal, Inc.*, 2012 U.S. Dist. LEXIS 54435 at *15-*19 (N.D. Ala. 2012) (providing a limiting instruction where certain evidence might lead the jury to be confused regarding the court's claim constructions).

[21] The University and TissueGen are ***not*** asking the Court to strike Dr. Mooney on the issue of whether the SYNERGY™ stents include two "immiscible" phases in this motion or on the subject of invalidity.

Ladies and Gentlemen of the jury. The Court instructs you that the testimony you heard from Dr. Mooney, expert witness for the Defendants regarding the issue of whether the SYNERGY™ stents accused of infringement include a fiber as claimed in the '296 patent has been struck from this case. You are not to consider Dr. Mooney's testimony on the subject of whether the Accused Products include a fiber. In your deliberation of the case, you are to give Dr. Mooney's testimony on the subject no weight.

The University asks the Court to rule on this issue before Dr. Mooney takes the stand again. Time is literally running out. The University should not be required to spend its limited time cross-examining Dr. Mooney on this issue, nor should the University be required to use any of its time to rebut testimony that a fiber can be made using processes other than spinning techniques as that was not an issue that was ever supposed to be a part of these proceedings and no time should have to be devoted to it.[22]

## IV. CONCLUSION

For the above stated reasons, the Court should grant Plaintiffs' Motion to strike Dr. Mooney's testimony on the issue of whether the SYNERGY™ stents include a "fiber" as claimed in the '296 patent and for an instruction that Dr. Mooney's testimony on the issue be disregarded by the jury in their deliberations.[23]

[22] See n. 1 and n. 2 *supra*.

[23] The University and TissueGen reserve their rights to seek fees and costs for the misconduct demonstrated in this motion and continue to ask the Court to inquire into whether and to what extent Boston Scientific's counsel pre-planned these violations or if they were spontaneous by the witness.

Respectfully Submitted,

*/s/ Stamatios Stamoulis*

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**CERTIFICATE OF SERVICE**

I hereby certify that on January 29, 2023, the foregoing was served via electronic mail upon all counsel of record for the parties.

*/s/ Stamatios Stamoulis*
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